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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/649,399

08/26/2003

Ben-Zion Dolitzky

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EXAMINER

BERCH, MARK L

ART UNIT

PAPER NUMBER

1624

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/649,399	<b>Applicant(s)</b> DOLITZKY ET AL.	
	<b>Examiner</b> Mark L. Berch	<b>Art Unit</b> 1624	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04/20/2009; 04/23/2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 18,35 and 53-85 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 35 and 58 is/are allowed.
- 6) ☒ Claim(s) 18,53,56,57 and 59-85 is/are rejected.
- 7) ☒ Claim(s) 54 and 55 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04/20/2009 has been entered.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 74-76 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Pharmaceutically acceptable compositions cannot include unsafe organic solvents. Methanol is considered a toxin. Limitation to the ethanol solvate would overcome this rejection.

Claims 59, 62-64, 66-69 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 62 specifies heating the monohydrate at about 40°C to about 80°C to give form 1, now identified via the 15.5 and 15.9 numbers. According to the declaration of 19 April 2009, experiment 6, the monohydrate was heated at 45°C and Form 1 did not result. The specification has no working example to this process. If applicants wish to argue that the process in experiment 6 gave a product which had the 15.5 and 15.9 numbers but which is not form 1, they would need to show that they did in fact possess that form, since the specification does not seem to describe anything except forms I, II and II and the monohydrate. Accordingly, the statement in the specification is not credible, since it is contradicted by example 6. Accordingly, claim 64 is included, as it is based on that statement which is not credible.

Claims 59-61, 66-69, 72-77 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Art Unit: 1624

The ethanol solvate cannot be deemed enabled. Therefore, all claims which involve this compound, its synthesis or its use, are not enabled.

Aside from the monohydrate, the specification describes three forms, I, II which are forms of Famciclovir, and Form III, which is called a methanol solvate. See page 3, lines 1-9. Form III is also called a methanol solvate three times in the description of figures on page 6, and three times on page 8.

Confusing matter is a statement on page 7, lines 19-21 which states that Form III refers to both the ethanol and methanol solvates. Specifically: "Both of these solvates have the same physiochemical properties and the same XRD pattern." This statement cannot be taken correct on its face. Methanol is a toxin and ethanol is not; ethanol is a desiccant and methanol is not, and there are other differences, and therefore these do not have the same physiochemical properties. Hence, this sentence cannot be relied on. Further, having the same XRD pattern for two different compounds is very unlikely, although not theoretically impossible if the alcohol is at least partially disordered.

There are additional problems. The specification does not teach how to make the ethanol solvate. Page 11 states, "Crystalline solid famciclovir form II was crystallized from ethanol. Crystalline solid famciclovir form II was also crystallized from n-butanol." The second sentence makes it clear that Form II is not an ethanol solvate (Form II is never called in the specification a solvate). The first sentence then indicates that an ethanol solvate does not form from ethanol, and therefore, there is no teaching of how to form.

Page 12 states the following: "A mixture of crystalline solid famciclovir form III and form I was obtained by trituration of anhydrous famciclovir with ethanol.

A mixture of crystalline solid famciclovir form III and famciclovir monohydrate was obtained by trituration of anhydrous famciclovir in ethanol.”

These two sentences directly contradict each other. Hence, neither of them can be relied upon. In addition, these are both fairly inconsistent with the page 11 text. It seems very unlikely that trituration could produce the ethanol solvate when the more robust crystallization from ethanol failed to do so. See in this regard example 4 in which crystallization from ethanol produced form II. Note that the end provides, in effect, a trituration, as the crystals sit in the solvent. (The examiner notes that trituration with the similar solvent isopropanol produces Form 1, not a solvate). These are backed by examples 7, 8 and 9. These contain the remarkable results that a) the same product (Form III) is obtained regardless of whether methanol or ethanol is used and b) an experiment in which no water was employed, still produced the monohydrate. Therefore, these experiments cannot be relied upon. This point b) is an additional reason that claim 73 cannot be deemed enabled.

Applicants can overcome this by showing that they actually do have an ethanol solvate.

Claims 18, 53, 56-57, 60-72, 78-85 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 18, 53, 56-57, 60-72, 78-85 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1624

The forms in these claims are defined in terms on only two peaks. Two peaks are not necessarily enough to define a particular crystalline form, since two forms could coincidentally have the same two peaks within the margin of error. For example, Form I and Form II both have 17.0 and 25.6. There applicants may be claiming:

A. All forms with e.g. 6.6 and 13.0, regardless of whether these are I, II or III.

B. Only I, II and III.

Since it is unclear whether A or B is the case, the claims are indefinite.

If A is the case, then the claims are clearly not enabled, since applicants do not describe, nor do they teach, forms other than I, II or III.

If B is the case then the claims are indefinite under the second branch of paragraph 2 as well, since applicants intend B, but literally state A. The claims “must set forth the subject matter that Appellants regard as their Invention.” This is a separate requirement from definiteness.

### ***Specification***

Page 8, line 11 is incorrect. The two following paragraphs describe DSC results, which are thermoanalytical, but are not thermogravimetric, since nothing is weighed in DSC.

### ***Claim Objections***

Claims 54-55 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to /Mark L. Berch/ whose telephone number is 571-272-0663. The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on (571)272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark L. Berch/  
Primary Examiner  
Art Unit 1624

5/13/2009